Controlled Copy

Directorate General of Drug Administration
(DGDA)
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Dhaka-1000

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Title : *Pzz³wfwËK JIa Drcv`‡bi wb‡`©wkKv*

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Date :	Date :	Date :

01| fwgKv t

JIa bxwZ 2005 Ges Drugs (Control) (Amendment) Act, 2006 *†gvZv‡eK JIa ckvmb Awa`ßi Pzz³wfwËK JIa Drcv`‡bi AbygwZ c`vb K‡i|*

1.1 RvZxq Iln bxwZ 2005-G Pzy³wfwËK JIa Drcv`‡bi welq DwjøwLZ welqvw` t

1.1.1 chy³ n¯vši A_ev be-D™¢weZ Ilagmg‡ni jf¨Zv wbwðZ Kivi j‡¶¨ evsjv‡`‡k Drcv`b BDwbU †bB Ggb we‡`kx †Kv¤úvbx‡K Zvi wbRm¦ M‡elYvjä Rxeb i¶vKvix Ilyx Dnvi cQ›` Abyhvqx G‡`‡ki †h †Kvb Askx`v‡ii m‡½ jvB‡mÝ c`vb Pzy³ i AvIZvq ¯nvbxqfv‡e Drcv`‡bi AbygwZ c`vb Kiv n‡e hw` D³ Ilyx GKB cY¨bv‡g Kgc‡¶ wb‡gewYZ `ÿyU DbZ‡`‡k wbewÜZ I evRviRvZ _v‡K t hy³ ivó, hy³ ivR¨, mBRvij¨vÛ, Rvgvbx, dvÝ, Rvcvb I A‡÷wjqv|

1.1.2 evsjv‡`‡ki ewn‡i wecb‡bi c‡qvR‡b evsjv‡`‡k Drcv`b BDwbU †bB Ggb †h †Kvb we‡`kx Ilyx †Kv¤úvbx‡K Dnvi cQ›` Abyhvqx †h †Kvb Askx`v‡ii mv‡_ jvB‡mÝ c`vb/gvïj c`vb Pzy³ i AvIZvq ¯nvbxqfv‡e †h †Kvb Ilyx Drcv`‡bi AbygwZ †`Iqv n‡e|

1.1.3 evsjv‡`‡k Drcv`b cv‡Èi AwaKvix ¯nvbxq I we‡`kx Dfq cKvi †Kv¤úvbx¸‡jv‡K gvïj A_ev Pzy³-Drcv`b e¨e¯nvax‡b (Toll/Contract Manufacturing Arrangement) *Zv‡`i cQ›`g‡Zv Ab¨ †h †Kvb Drcv`b cv‡È Ilyx c¯ZyZ Kivi AbygwZ c`vb Kiv n‡e|*

1.2 Drugs (Control) (Amendment) Act, 2006 *G Pzz³wfwËK JIa Drcv`‡bi Rb¨ ewYZ wb‡`©kbv t*

Manufacturer of Drugs under licensing agreement etc. subject to the approval of the licensing authority:-

1.2.1 Foreign Manufacturer may be allowed to manufacture any drug under licensing agreement with any manufacturer in Bangladesh if the drug is its research product and is registered under the same brand name in any of the countries specified under sub-section (1A) of section 5”

1.2.2 A manufacturer in Bangladesh may be allowed to manufacture any drug under any written contract with any pharmaceutical manufacturing plant in Bangladesh.

1.3 Pz³ ভিত্তিক ঔষধ উৎপাদন প্রক্রিয়ায় বিভিন্ন প্রতিষ্ঠানের অব্যবহৃত সুবিধা Ges Drcv`b ¶gZv Kv‡R jvwM‡q wecyj cwigvY Jla Drcv`b m¤¢e, G‡Z wewb‡qvMKZ.A‡_i h_v‡cvhy³ e¨envi Ges cÖwZ ˆe‡`wkK gy`ªvi mvkÖq nq| cÖ_eªvi wewfbœ †`‡k Pz³ ভিত্তিক ঔষধ উপাদনের নজির রয়েছে এবং দেশেও এ প্রক্রিয়া চলমান আছে।

myùwi`ó MvBWjvBb bv _vKvq Pz³wfwËK Jla Drcv`b e¨e¯'v h_vh_fv‡e gwb‡Uvi I wbqšÎY Kiv m¤¢e n‡”Q bv| we`¨gvb Jla bxwZ Ges Jla AvBb‡bi wfwË‡Z Pz³wfwËK Jla Drcv`‡bi AbygwZ c`v‡bi Rb¨ myùwi`ó ক্রাইটেরিয়া নির্ধারণ এবং চুক্তি c`vbKvix I MnYKvix cÖwZôvbmg~n gwb‡Uvq‡bi wbwg‡Ë GKwU ÷¨vÛvW MvBWjvBb cÖYqb Avek¨K| GKwU cÖgvZ (÷¨vÛvW) MvBW jvBb KvhKi wbqšÎY e¨e¯'v cÖwZôvq Ges gvb m¤úbœ Jla Drcv`‡b mnvqK n‡e|

02| D‡Ïk¨ t

2.1 Pz³wfwËK Drcvw`Z Jl‡ai gvb wbwðZ Kiv|

2.2 KvhKi wbqšÎY e¨e¯'nv cÖwZôv Kiv|

2.3 Pz³e× cÖwZôvbmg‡ni msw¯kó myhvM-myweav gwb‡Uvq‡b myùwi`ó wb‡`kbv AbymiY Kiv|

2.4 Pz³ MnYKvix cÖwZôv‡bi Drcv`b I gvb-wbqšÎY K¨vcvwmwU h_vh_fv‡e gwb‡Uvqb Kiv|

2.5 Pz³ MnYKvix cÖwZôv‡bi Drcv`b I gvb-wbqšÎY e¨e¯'vq wRGgwc ev¯ÍZevqb wbwðr Kiv|

2.6 cÖwZôvbmg‡ni AvBbMZ `vq I `vwqZ wbiƒcb Kiv|

2.7 Pz³e× cÖwZôvbmgn‡K myùwi`ó w`K wb‡`kbv c`vb Kiv|

2.8 Pz³wfwËK Drcv`‡bi weåvwšZ `~i Kiv|

03| GjvKvmgn t

3.1 ***AbygwZ, AvBb, wewa I bxwZ t***
WWM A¨v± 1940, WWM i‡j 1945, ‡e½j WWM i‡j 1946, Jla (wbqšÎY) Aa¨v‡`k 1982 Ges Jla bxwZ 2005 I Drugs (control) (Amendment) Act, 2006|

3.2 ***Pz³i aiY t*** gvïj c`vb ev jvB‡mÝ c`vb-Gi AvIZvq (Under License/Toll Manufacture/Contract Manufacture)|

3.3 ***Pz³i welq t*** WWM cWv± (†WW‡Rm dg) I WWM mve÷¨vÝ (Jl‡ai KvPvgvj) Drcv`b, D”P chy³i Jl‡ai ‡¶‡Î cix¶v I we‡kIY Pz³wfwËK KgKv‡Ûi AvIZvfy³ n‡e|

3.4 ***Pz³bvgv t*** Pz³ c`vbKvix I Pz³ MnYKvix cÖwZôvb `yÕUi g‡a¨ GKwU Pz³bvgv m¤úv`b Ki‡Z n‡e| D³ Pz³bvgvq wbgewYZ kZvw` _vK‡Z n‡e|

3.4.1 m¤úvw`Z Pz³i †gqv` n‡e Kgc‡¶ `yB eQi Ges m‡ev”P cuvP eQi| Pz³ bevqb‡hvM¨ n‡e|

3.4.2 Pv³e× c‡`i KvPvgvj msi¶Y, cWv± †Wfjc‡g›U, Drcv`b, gvb-wbqšY, gvb wbðZKiY Ges e¨vP wiwj‡Ri wel‡q Dfq cwZôv‡bi mywbw`ó `wqZ Pv³bvgvq D‡jL Ki‡Z n‡e|

3.4.3 cWv± †Wfjc‡g›U, ÷¨wewjwU ÷¨wW, c‡mm †fwj‡Wkb, GbvjvBwUK¨vj †g_W ‡fwj‡Wkb/ †fwiwd‡Kkb, WK‡g›U cYqb Ges †Uwbs-Gi `wqZ Pv³bvgvq mywbw`ófv‡e D‡jL _vK‡Z n‡e|

3.4.4 Pv³ MnYKvix cwZôv‡bi Pv³e× c‡`i Drcv`b I gvbwbqš‡Yi me‡gvU ¶gZv Ges Ae¨eüZ ¶gZv Pv³bvgvq D‡jL Ki‡Z n‡e|

3.4.5 Pv³e× c‡`i KvPvgvj msMn, msi¶Y Ges wiwj‡Ri `wqZ, Drcvw`Z c‡`i msi¶Y I wiwj‡Ri `wqZ Pv³bvgvq D‡jL Ki‡Z n‡e|

3.4.6 e¨vP †iKW Ges Avbylw½K WK‡g›U msi¶‡Yi `vq Ges `wqZ Pv³bvgvq D‡jL Ki‡Z n‡e |

3.5 Drcv`b I gvbwbqšY e¨e¯vi †KvqvwjwU AwWU-Gi `wqZ Pv³bvgvq D‡jL Ki‡Z|

3.6 †KvqvwjwU g¨vbyqvj t Pv³ MnYKvix cwZôv‡bi †KvqvwjwU g¨vbyqv‡j Pv³e× c‡`i gvbwbqšY I gvb wbwðZKi‡Yi wel‡q w`K wb‡`©kbv _vK‡Z n‡e|

3.7 Pv³ c`vbKvix I MnYKvix Dfq cwZôv‡bi mvBU gv÷vi dvBj-G Pv³e× c‡`i Z_¨w` D‡jL _vK‡Z n‡e|

3.8 KvPvgvj cix¶v I we‡kølYKvix cwZôvb KvPvgv‡ji wi‡Ubkb m¨v¤új msi¶Y Ki‡e|

3.9 Pv³ c`vbKvix Ges MnYKvix Dfq cwZôv‡b Drcvw`Z Jl‡ai wi‡Ubkb m¨v¤új msi¶Y Ki‡Z n‡e|

3.10 e¨vP WK‡g›Um-Gi gš-Kwc Pv³`vZv cwZôvb Ges cwZwjwc Pv³ MwnZv cwZôvb msi¶Y Ki‡e|

3.11 Dfq cwZôvb †hŠ_fv‡e Pv³e× c‡`i †KvqvwjwU AwW‡Ui c‡UvKj cYqb Ki‡e Ges †KvqvwjwU AwWU cwiPvjbv Ki‡e|

3.12 Pv³ c`vbKvix cwZôvb KvPvgvj, c¨wKs †g‡Uwiqvj, Bbc‡mm K‡›Uvj, evé cWv± Ges wdwbmW cWv‡±i †¯úwmwd‡Kkb †mU-Avc Ki‡e| G wel‡q c‡qvR‡b Pv³ MnYKvix cwZôv‡bi mnvqZv MnY Ki‡e|

3.13 WHO-Gi wRGgwc MvBW jvB‡bi Contract Production and Analysis-wk‡ivbv‡g ewYZ hveZxq kZvw` Dfq cwZôvb Abymi Y Ki‡e|

04| †i¸‡jUix K‡›Uvj t

4.1 ïaygvÎ mgc×wZi Jla Drcv`bKvix cwZôv‡bi g‡a¨ ôPv³wfwËK Jla Drcv`bô-Gi Pv³ m¤úv`b Kiv hv‡e| A_vr A¨v‡jvc¨vw_K-Gi mv‡_ A¨v‡jvc¨vw_K, nvevj-Gi mv‡_ nvevj, BDbvbx-Gi mv‡_ BDbvbx, Avqy‡e©w`K-Gi mv‡_ Avqy‡e©w`K I †nvwgIc¨vw_K-Gi mv‡_ †nvwgIc¨vw_K|

4.2 Pv³`vZv cwZôvb‡K Pv³e× Jlamg‡ni Pv³wfwËK Drcv`‡bi AbygwZ †P‡q Jla ckvm‡b Av‡e`b `wLj Ki‡Z n‡e| wK Kvi‡Y Pv³wfwËK Drcv`‡bi c¯Zve Kiv n‡q‡Q, KZ mg‡qi Rb¨ Pv³wfwËK Drcv`b Ki‡Z Pvq Zv Av‡e`‡b D‡jL Ki‡Z n‡e|

4.3 Pv³ `vZv I Pv³MnxZv cwZôv‡bi g‡a¨ m¤úvw`Z Pv³bvgv Jla ckvmb Awa`ßi KZ…K Abyţgvw`Z n‡Z n‡e| Pv³i ‡gqv` DËxY nIqvi c‡e †gqv` e"×i Rb¨ Av‡e`b `wLj Ki‡Z n‡e Ges c¯ZweZ †gqv‡`i Abyţgv`b MnY Ki‡Z n‡e|

4.4 Pv³i †gqv`Kv‡j Dfq cwZôvb‡K Pv³bvgvi kZvw` †g‡b Pj‡Z n‡e|

4.5 mvaviYfv‡e ¯vbxq Drcv`bKvix cwZôv‡bi †¶‡Î wØc¶xq Pv³ MnY Kiv n‡e, wÎc¶xq Pyw³ (Third Party Agreement) wbiærmvwnZ Kiv n‡e| RvZxq `y‡hvMKvjxb AZ¨vek¨K n‡j wÎc¶xq Pyw³i wel‡q we‡ePbv Kiv n‡e|

4.6 we‡`kx cwZôv‡bi †¶‡Î wØc¶xq I wÎc¶xq Pvy³ (Third Party Agreement) MnY Kiv n‡e|

4.7 evsjv‡`‡k Drcv`b BDwbU ‡bB Ggb we‡`kx †Kv¤cvbx‡K Zvi M‡elYvjä Rxebi¶vKvix Jla Zvi cQ›` Abyhvqx G‡`‡ki †h †Kvb Askx`v‡ii m‡½ jvB‡mÝ c`vb/Pvy³i AvIZvq ¯nvbxqfv‡e Drcv`‡bi Abygwz c`vb Kiv n‡e|

4.8 Pzw³ MnxZv cwZôvb ÔPzw³e×Õ GKB c` Ab¨Î †Uvj/KÈv± wfwËK Drcv`b Ki‡Z cvi‡e bv| Pzw³`vZv cwZôvb GKB m‡½ GKwU c` GKwaK cwZôv‡bi mv‡_ †Uvj/KÈv± wfwËK Drcv`b Ki‡Z cvi‡e bv|

4.9 we‡`kx cwZôvb KZK c`Ë jvB‡m‡Ýi AvIZvq Pzw³wfwËK Drcv`‡bi †¶‡Î jvB‡mÝcvß cwZôvb Pzw³`vZv cwZôvb wnmv‡e we‡ewPZ n‡e Ges KvRgvj Avg`wbi wbwg‡Ë Jla ckvmb †_‡K Abyhvgv`b MnY Ki‡e|

4.10 Pzw³Kvjxb mg‡q Pzw³`vZv I Pzw³MnxZv cwZôv‡bi Drcv`b jvB‡mÝ ˆea †gqv‡`i n‡Z n‡e|

4.11 Pzw³`vZv I Pzw³MnxZv cwZôv‡bi Pzw³ †gvZv‡eK †Kvb Pzw³e× c‡`i wewfbœ KgKvÛ Dfq cwZôv‡b m¤úvw`Z n‡j †m †¶‡Î Dfq cwZôv‡bi mswkó welqK mycwi`k‡bi gva¨‡g hvPvB Kiv n‡e| ‡hgb- Pzw³`vZv cwZôvb স্ট্যাবিলিটি স্টাডি কার্যক্রম, প্রসেস ভেলিডেশন, Gbvjv‡BwUK¨vj †g_W ‡fwj‡Wkb/†fwidKkb BZ¨vw` কার্যক্রম cwiPvjbv Ki‡j †m †¶‡Î Pzw³`vZv cwZôv‡bi Dwjwl‡Z welqK mycwi`k‡bi gva¨‡g gj¨vqb Kiv n‡e|

4.12 Pzw³MnxZv cwZôv‡bi Jla Drcv`b K¨vcwmwU m¤ú‡K we¯Zvwi‡Z Z_¨vw` Jla ckvm‡b `wLj Ki‡Z n‡e|

4.13 Pzw³MnYKvix cwZôv‡bi KviLvbv cwi`k‡bi gva¨‡g mweK mycwi`k gj¨vqb K‡i Pzw³wfwËK Drcv`‡bi Abygwz c`vb Kiv n‡e|

4.14 cwi`kbKv‡j Pzw³MnYKvix cwZôv‡bi KviLvbvi cwimi, cwi‡ek, ¯wcZ ‡gwkbvixi Drcv`b I gvb- wbqšY ¶gZv, g¨v‡Uwiqvj n¨vÛwjs e¨e¯v I †jvKe‡ji K¨vcwmwU hvPvB Ki‡Z n‡e|

4.15 Pzw³wfwËK Drcw`Z c‡`i G¨v‡b·vi Ges ‡gvoKmvgMx‡Z Pzw³i welqwU ¯úófv‡e D‡jL Ki‡Z n‡e (†hgb Manufatured by 'X' for 'Y', Manufactured for 'X' by 'Y' BZ¨vw`)|

4.16 Under Lisensing প্রক্রিয়ায় ঔষধ উৎপাদনের ক্ষেত্রে c‡`i G¨v‡b·vi Ges ‡gvoKmvgMx‡Z jvB‡mÝ c`vbKvix cwZôv‡bi bvg D‡jL Ki‡Z n‡e|

4.17 Pzw³e× †Kvb c` gvb ewnfyZ/†fRvjh¨³ n‡j Dfq cwZôvb‡K AvBb ‡gvZv‡eK `vq-`wqZ enb Ki‡Z n‡e|

4.18 †Kvb Kvi‡Y Pzw³i Aemvb ev Pzw³ ewZj Ki‡j Jla ckvmb‡K AewnZ Ki‡Z n‡e|

4.19 Pzw³bvgvi †Kvb kZ cwieZb/cwieab/ms‡hvRb-we‡qvRb Ki‡j, Pzw³e× c‡`i †Kvb cwieZb Ki‡j Jla ckvmb‡K AewnZ Ki‡Z n‡e Ges Abyhvgv`b MnY Ki‡Z n‡e|

05| Pzw³wfwËK Jla Drcv`‡bi †¶‡Î G MvBW jvB‡b ewYZ wb‡`kvewj Pzw³ MnYKvix I Pzw³ c`vbKvix cwZôvbmgn-h_vh_ fv‡e Abyhvi Y Ki‡e|

06| c‡qvR‡b D³ MvBW jvBb mg‡q mg‡q nvjbvMv` Kiv n‡e|

07| cYxZ ÷¨vÛvW di‡gU (Kwc msh¨³) Abyhvqx mswkó c¶‡K Pzw³ m¤úv`b Ki‡Z n‡e|

Format for Preparing
A Contract (Toll) Manufacturing Agreement

Preamble: The name of the Contract Giver (CG) and the Contract Acceptor (CA) involved with their registered addresses. To include the purpose of the Contract and the desire of the parties involved.

Contents:

1. **Definition:** Definition of all the relevant terms used in the Contract should be given.
2. **Appointment:** i) Period of Contract; ii) Site of Manufacturing; and iii) Purpose; to be included.
3. **Technology, Manufacturing Instructions, Standard and Guidelines:** Responsibilities of the individual parties to be defined. To mention who will provide what for the manufacture of the products.
4. **Manufacture of the products:** To mention that the CA will manufacture with its facilities/equipment/utilities for bulk processing and packaging using APIs and materials provided by the CG. Also to mention about a Quality Agreement as given in Appendix D.
5. **APIs and other materials:** Who will provide what should be defined.
6. **Forecast and Orders:** To be provided by CG and the period and timing to be mentioned.
7. **Storage and Stock:** Responsibilities of both the parties related to APIs, Excipients, Packaging Materials, Finished Products, and Quarantine Stock before release, should be clearly mentioned.
8. **Delivery of the Products:** Procedure for delivery of the products by the CG should be defined along with the transfer documents and compliance of VAT payment formalities.
9. **KPIs (Key performance indicators), Yield and Improvement:** Procedure for addressing these parameters should be included.
10. **Quality:** The parties should enter into the Quality agreement as given in Appendix D. Responsibilities of the parties for maintaining records, analysis, in-process checks, release, rejection, transfer, supervision should be defined.
11. **Non-conformity:** All batches of product(s) delivered by CA to the CG shall comply with the specifications. However if there is any deviation then how to address should be defined.
12. **Manufacturing Fees and Payments:** Should be clearly defined and attached as Appendix.
13. **Intellectual Property Rights– Authorizations:** Responsibility of the CG for product registrations and compliance as per laws of Bangladesh.
14. **Audit – Inspection:** Role of the CG and acceptance by the CA should be defined.
15. **Confidentiality:** Responsibility related to disclosure of the information related to the Contract should be defined.
16. **Warranties and Representations:** CA should warrant and represents that all products manufactured and delivered pursuant to the Contract should conform to the specifications and manufactured in accordance with the GMP and all applicable laws and regulations relevant to the manufacture of the products.Safety, health and environment issues are the responsibility of the CA. Whereas CG should warrant that it is the owner of the intellectual property rights and that APIs and all materials provided are compliant and it is the owner of the products and the products are duly registered.
17. **Liability:** Responsibility of the CA for material loss during production or delivery. Whereas CG will indemnify CA against all claims related to the uses of the products by third parties. However insurance policies may be taken by the individual parties for their own protection.
18. **Force Majeure:** To be included as in any Standard Contract.

19. **Term and Termination:** Effective Date and the period of Contract, the renewal procedure and responsibilities to be defined.
20. **Consequence of Termination:** Action involved and responsibility of the parties to be defined. Notification to the regulatory authority by both CG and CA.
21. **Applicable Law and Dispute Resolution:** Provisions for resolving any dispute amicably and if failed should be through arbitration should be defined.
22. **Miscellaneous:** Terms related to stipulations with other laws, assigning, modification to the Contract, notices, reference in promotional materials, discrepancies to be addressed.
23. **Signatures and Witnesses:** Signatures, names and designations of the signatories and witnesses to be included.

24. **Appendices:**

    A. Product List
    B. API Specifications
    C. Manufacturing Instructions and Storage Condition
    D. Quality Agreement
        a) Definitions
        b) Basis
        c) Object
        d) Starting and Packaging Materials
        e) Manufacture, Manufacturing Procedures and Manufacturing Records
        f) Quality Control
        g) Storage
        h) Change Control
        i) Contracting of third parties
        j) Inspections
        k) Complaints and Recall
        l) Concluding Provisions
        m) Appendices of Quality Agreement
            1. Persons Responsible from CG and CA should be listed
            2. Products ordered and responsibilities: i) Primary Packaging; ii) Secondary Packaging; iii) Release
            3. Division of Pharmaceutical Responsibilities: CG and CA *(a blank format provided)*
            4. Suppliers of starting materials, primary, secondary and other packaging materials
    E. Manufacturing Fees
    F. KPIs
    G. Responsibilities of Supply and Responsibilities of Manufacturing

Appendix 3
Division of pharmaceutical responsibilities
(mark the square for the responsible party)

Contract Giver (CG):

Contract Acceptor(CA):

	Contract Giver(CG)	**Contract Acceptor (CA)**
Compliance with the registration documents	☐	☐
Division of pharmaceutical responsibilities:		
Active ingredient (s)		
Specification	☐	☐
Supply/Procurement	☐	☐
Testing	☐	☐
Transport conditions	☐	☐
Retention samples	☐	☐
Other starting materials:		
Specification	☐	☐
Supply/Procurement	☐	☐
Testing	☐	☐
Transport conditions	☐	☐
Retention samples	☐	☐
Primary packaging materials:		
Specification	☐	☐
Clearance for printing	☐	☐
Supply/Procurement	☐	☐
Testing	☐	☐
Retention samples	☐	☐
Secondary packaging materials		
Specification	☐	☐
Clearance for printing	☐	☐
Supply/Procurement	☐	☐
Testing	☐	☐
Retention samples	☐	☐
Other packaging materials:		
Specification	☐	☐
Clearance for printing	☐	☐
Supply/Procurement	☐	☐
Testing	☐	☐

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Appendix 3

	Contract Giver (CG)	Contract Acceptor (CA)
Package insert:		
Specification	☐	☐
Clearance for printing	☐	☐
Supply/Procurement	☐	☐
Testing	☐	☐
Finished product:		
Specification	☐	☐
Packaging prescriptions (master instruction)	☐	☐
Packaging prescriptions (actual performance)	☐	☐
In-process control (master instruction)	☐	☐
In-process control (actual performance)	☐	☐
Finished product analysis	☐	☐
Packaging/packaging record	☐	☐
Assignment of batch number	☐	☐
Final inspection	☐	☐
Release for dispatch	☐	☐
Retention samples	☐	☐
Final release to market	☐	☐
Transport conditions	☐	☐
Post marketing stability surveillance	☐	☐
*Process deviation / investigation report	☐	☐
Finished product:		
Manufacturing record, complete		
In-process control records		
Packaging record, complete	☐	☐
Packaging record, extract	☐	☐
Certificate of Analysis	☐	☐

Other agreements / Special arrangements: None

*if any

Format For Preparing
A Contract (Toll) Manufacturing Agreement

1. **Definition:** ----------

2. **Appointment:** ----------

   i. Period of Contract:----------

   ii. Site of manufacturing: ----------

   iii. Purpose: ----------

3. **Technology**

   i. Manufacturing Instructions :----------

   ii. Standard and Guidelines:----------

4. **Manufacture of the products:** ----------

5. **APIs and other materials:** ----------

6. **Forecast and Orders:** ----------

7. **Storage and Stock:** ----------

8. **Delivery of the Products:** ----------

9. **KPIs (Key performance indicators), Yield and Improvement:** ----------

10. **Quality:** ----------

11. **Non-conformity:** ----------

12. **Manufacturing Fees and Payments:** ----------

13. **Intellectual Property Rights – Authorizations:**------

14. **Audit – Inspection: Confidentiality:** ----------

15. **Warranties and Representations:** ----------

16. **Liability: ----------**

17. **Force Majeure: ----------**

18. **Term and Termination**:---------- ----------

19. **Consequence of Termination:** ----------

20. **Applicable Law and Dispute Resolution:** ----------

21. **Miscellaneous:** ----------

22. Signatures and Witnesses: ----------

23. **Appendices**:----------