Food & Drug Administration
Divisin of Drug Control
Drug Registration Section

PRODUCT INFORMATION CHECK LIST

Name of Drug..... Owner of Drug.....
Manufacturer .....
Applicant Name & .....

(I) Administrative Documents

(1)	Letter of authorization	(1)
(2)	Company Profile	(2)
(3)	Certificate of pharmaceutical product	(3)
(4)	G.M.P certificate	(4)
(5)	Manufacturing Licence	(5)
(6)	Proforma statement:	(6)
(7)	Summary Drug Information Sheet	(7)

Remarks on administrative documents.....
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(II) Pharmaceutical Doucments

(1)	Name of Drug, its composition and physical, chemical properties of active substances and excipients	(1)
(2)	Analytical method for active substances and excipients	(2)
(3)	Standard control procedure on raw materials	(3)
(4)	Raw materials specifications	(4)
(5)	Specimen Q.C report on raw materials	(5)
(6)	Manufacturing process	(6)
(7)	Standard procedure for in-process quality control	(7)
(8)	Specimen in-process Q.C report	(8)
(9)	Finish product specifications	(9)
(10)	Disintegration and dissolution profile	(10)
(11)	Analytical method for finished product	(11)
(12)	A sample copy of certificate of analysis	(12)
(13)	Stability test report	(13)
(14)	Packaging specifications	(14)
(15)	Specimen package, label, & package insert	(15)
(16)	Q.C procedure & report on label, and packaging	(16)

Remarks on pharmaceutical documents.....
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(III) Pharmacological Documents

(1)Data on basic pharmaceutical and microbiological studies

(a)	Taxicity data	(a)
(b)	Teratogenicity data	(b)
(c)	Mutagenceity	(c)
(d)	Data on efficacy and general pharmacology	(d)
(e)	Data on pharmacokinetics	(e)

(2)Data on clinical studies

(a)	Phase I, II, Phase III, IV	(a)
(b)	Clinical pharmacokinetics	(b)
(c)	Bio-availability	(c)
(d)	Drug interaction	(d)

Remarks on pharmacological documents.....